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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,253	01/19/2001	Thomas R. Cech	015389002921	8469

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,253	CECH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,13,14 and 18-24* is/are pending in the application.

4a) Of the above claim(s) *13,14 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application. Applicant's submission filed on April 15, 2003 has been entered.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 8 and 21-24, drawn to methods for detecting a polynucleotide encoding at least a portion of a telomerase, classified in Class 435, subclass 6.

II. Claims 13 and 14, drawn to antisense nucleic acids, classified in Class 536, subclass 23.5 and 24.5.

III. Claims 18 and 19, drawn to antibodies, classified in Class 530, subclass 387.

IV. Claim 20, drawn to methods to detect a protein using an antibody, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for therapeutic methods.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of invention III are not required to practice the methods of invention I.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of invention I and IV each require the use of different reagents, require performing distinct method steps and have different objectives.

Inventions II and III are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas invention III is drawn to antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids arranged in a specific 3-dimensional structure, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while antibodies may be utilized in ligand binding assays or to generate antibodies. Synthesis of the antibodies of invention III do not require the particular products of the nucleic acids of invention I since the antibodies of invention III can be isolated from natural sources or chemically synthesized.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antisense nucleic acids of invention II are not required to practice the methods of invention IV.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for therapeutic purposes.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

During a telephone conversation with Michael Schiff, Applicants verified that invention I, claims 8 and 21-24 were to be examined herein. Claims 13, 14, and 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide basis for the amendment to the claims to recite a method for detecting a polynucleotide sequence encoding at least a portion of a telomerase wherein said method comprises comparing the sequence of a polynucleotide from a sample to the sequence of telomerase motifs 0, 1, 2 and 3 and determining that said sample contains a polynucleotide encoding at least a portion of a telomerase if said sequence contains motifs 0, 1, 2 and 3. The specification as originally filed provides basis for the concept of detecting a polynucleotide encoding at least a portion of a telomerase wherein said method comprises hybridizing a probe, such as a probe consisting of the sequence of SEQ ID NO: 100, to a polynucleotide from a biological sample and detecting the presence of a hybridization complex between the probe and the polynucleotide as indicative of the presence of a polynucleotide encoding at least a portion of a telomerase. The specification (e.g. pages 94-95) teaches that telomerase proteins have highly conserved regions of amino acid sequence and the specification provides an alignment of telomerase sequences from several different eukaryotes. The specification (page 24-25) states that "(a)s shown in Figure 25, there are regions that are highly conserved among these proteins. For example, as shown in this Figure, there are regions of identity in 'Motif 0,' 'Motif 1,' 'Motif 2,' and 'Motif 3.' The identical amino acids are indicated with an asterik (*), while the similar amino acid residues are indicated by a circle (•). This indicates that there are regions within the telomerase motifs that are conserved among a wide variety of eukaryotes, ranging from yeast to ciliates, to humans. It is likely that additional organisms will likewise contain such conserved regions of sequence." The specification also states that the present invention describes the use of the 123 kDa reverse transcriptase motifs in a method to identify similar motifs in organisms that are distantly related to Euplotes (e.g.,

Oxytricha), as well as organisms that are not related to Euplotes (e.g, Saccharomyces, Schizosaccharomyces, humans, etc.)." However, the reverse transcriptase motifs appear to be distinct from the telomerase specific motifs since 'motif 0' is defined as being specific to telomerase and not generally found in other reverse transctiptases. Accordingly, while the specification teaches that these conserved sequences are present in a wide variety of eukaryotes, the specification does not teach methods of using the presence of each of the motifs 0, 1, 2 and 3 to detect a polynucleotide encoding at least a portion of a telomerase. There is no disclosure in the specification as originally filed of a method for detecting a polynucleotide encoding a telomerase wherein detection of the polynucleotide is made on the basis of the presence of motifs 0, 1, 2 and 3.

4. Claims 8 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for detecting a polynucleotide sequence encoding at least a portion of a telomerase wherein said method comprises comparing the sequence of a polynucleotide from a sample to the sequence of telomerase motifs 0, 1, 2 and 3 and determining that said sample contains a polynucleotide encoding at least a portion of a telomerase if said sequence contains motifs 0, 1, 2 and 3. The specification (page 24-25) teaches that the telomeras amino acid sequence of several organisms has been compared and that regions of sequence conservation have been identified. In particular, Figure 25 provides a comparison of 4 telomerase amino acid sequences. The alignment includes designations of motif 0, 1, 2 and 3. The identical

amino acids are indicated with an asterik (*), while the similar amino acid residues are indicated by a circle (•). However, Figure 25 and the teachings of the specification do not clearly set forth what is intended to be encompassed by 'Motif 0,' 'Motif 1,' 'Motif 2,' and 'Motif 3.' It is unclear as to what constitutes the first and last position for each motif. For example, for Motif 0, it is unclear as to whether this motif begins at "AKFL..." or begins at "LHW...". It is also unclear as to what would be the amino acid residue for each position within each motif. For example, it is unclear if the motif may include any combination of the conserved and/or similar amino acid residues set forth in Figure 25 or if the motifs include only the particular amino acid residues set forth for the sequences of the human, tez1, EST2 or p123 telomerase proteins. When the recited sequence includes a "-", it is unclear as to whether the motif may include any amino acid residue at this position or if an amino acid residue is deleted and the flanking amino acid residues must be identical to those set forth in the figure. Additionally, figure 41 provides a comparison of 3 telomerase catalytic subunits. Below the headings of 'Motif 1,' 'Motif 2,' and 'Motif 3,' the figure includes the recitation of 'p_hh_h_K,' 'hR_h,' and 'h__hDh__GY__h,' respectively. However, the specification does not clarify whether these sequences constitute 'Motif 1,' 'Motif 2,' and 'Motif 3,' and the specification does not clearly set forth the relationship between these sequences of Figure 41 and the sequences/motifs in Figure 25. Figure 48 also includes a line reciting "Motif-1" but the sequence of the motif is not given. A consensus sequence of "FFYTE" is listed but it is not clear as to whether this constitutes the sequence of 'Motif 1.' Figure 48 also includes a listing of 'Motif 0' as "phhh_K__hRh__R" and states a consensus sequence of "R_PK__RI." It is unclear as to whether each of these alone may constitute 'Motif 0,' or if 'Motif 0' is intended to include the remaining flanking amino acids

listed in Figure 48. Lastly, the specification provides information regarding the conserved amino acid residues in the telomerase proteins, but does not teach the identity of conserved nucleotide residues. The claims require comparing a sample nucleotide sequence to telomerase motifs 0, 1, 2 and 3. Yet, the telomerase motifs have not been defined in terms of their nucleotide sequence. For each of these reasons, it is unclear as to what is intended to be encompassed by motifs 0, 1, 2 and 3. To practice the claimed invention requires knowledge of the specific amino acid residues of motifs 0, 1, 2, and 3. However, the specification does not provided sufficient guidance to enable the skilled artisan to determine what constitutes motifs 0, 1, 2 and 3. In view of the lack of disclosure and guidance provided in the specification, one of skill in the art could not practice the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 21-24 are indefinite and vague over the recitations of ' motifs 0,1, 2 and 3.' As discussed in detail in paragraph 4 above, it is unclear as to what constitutes the amino acid sequence of motifs 0, 1, 2 and 3. It is unclear as to the lengths of each of the motifs and as to which specific amino acid residues and combinations of amino acid residues make-up each of the individual motifs. Furthermore, the claims are indefinite and vague in that they refer to comparing the sequence of a polynucleotide to the sequence of telomerase motifs 0, 1, 2 and 3. However, the telomerase motifs set forth in the specification consist of an amino acid sequence

and not a nucleotide sequence. Thereby, it is not clear as to what is intended to be encompassed by comparing the nucleotide sequence of a sample polynucleotide to the amino acid sequence of a telomerase motif.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
July 14, 2003

CARLA J. MYERS
PRIMARY EXAMINER